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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,105

11/21/2003

Vasiliy Nosov

7678.714

1854

22913

7590

06/12/2006

WORKMAN NYDEGGER  
(F/K/A WORKMAN NYDEGGER & SEELEY)  
60 EAST SOUTH TEMPLE  
1000 EAGLE GATE TOWER  
SALT LAKE CITY, UT 84111

EXAMINER

WERNER, JONATHAN S

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/719,105	NOSOV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jonathan Werner	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/21/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 11/21/03 is noted. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-3, 7-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 6,395,551) in view of Patel (US 5,254,473). As to claims 1-2, Kipke discloses a preformed dental tray (10) sized and configured so that it is capable of being placed over at least a portion of a person's upper or lower teeth during a tray customization procedure; the dental tray comprising a polymeric material (column 3, lines 21-25) that is a polyethylene (column 3, line 50) and is capable of being softened in the presence of heat; and a color-changing indicator (14, Abstract). Kipke fails to disclose that said indicator is used to gauge a specified temperature range, however, Kipke refers to US patent No. 5,254,473 to Patel in which a color-changing temperature indicator is disclosed (Abstract, lines 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the color-changing indicator of Kipke by making it react to changes in temperature in order to monitor the time-temperature history of the device as taught by Patel. As to claim 3, the tray of Kipke does not itself change color when heated to within a certain customization temperature range. As to claims 7 and 8, Kipke discloses the indicator can either be removable or non-removably attached to the dental tray (column 7, lines 45-50). As to claim 9, Figure 1 of Kipke shows the indicator (14) is placed on the handle (12), separately from the tray. As to claims 10 and 11, Kipke discloses the indicator can reversibly change color (column 6, lines 25-29) or irreversibly change color (column 6, lines 56-62). As to claim 13, Patel discloses the color-changing temperature indicator changes from a first color to a second color when heated (see table, columns 6-7). As to claim 14, Table 1 of Patel shows that the

temperature indicator is capable of changing to a third color when heated. As to claim 15, Patel discloses numerous changes of color of the indicator based on temperature, wherein although a change in color from white to at least one of black or grey is not specifically disclosed, it would have been an obvious matter of choice to one having ordinary skill in the art at the time of the invention to include such colors. Examiner notes that the repeated occurrence of statements of intended use and functionality within all the claims, i.e. customizing the dental tray to be placed in a person's mouth, do not impose any structural limitations distinguishable over the prior art used, and as such are given little patentable weight since said prior art is capable of performing such functions.

4. Claims 4-6, 18, 21-22 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke in view of Patel as applied to claim 1 above, and further in view of Jacobs et al. (5,769,633). As to claims 4-6, Kipke and Patel disclose the dental treatment kit as previously described, but fail to show that the dental tray has a customization temperature in the range of about 110° to about 180° F. Jacobs however teaches a dental tray that is heated to a customization temperature in the range of 145° to about 160°F (Abstract, lines 4-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to have chosen such a customization temperature range for a dental tray since it makes the tray more formable and easier to mold to a desired shape as taught by Jacobs. As to claim 18, Jacobs also discloses the use of an outer support tray into which the preformed dental tray is placed

when heated and customized (see Abstract). As to claims 21 and 22, Jacobs further discloses placing the dental tray over the person's teeth when heated using hot water and forming an impression of the person's teeth within the dental tray (column 4, lines 3-13). As to claims 25-26, Jacobs discloses the step of removing the customized dental tray from the person's teeth after the impression has been formed and the dental tray cooled sufficiently so as to retain the impression (column 4, lines 21-24), and then trimming and scalloping the tray accordingly (column 6, lines 12-15).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke in view of Patel as applied to claim 1 above, and further in view of Hilsum et al. (US 4,468,137). Kipke and Patel disclose the dental treatment kit as previously described, but fail to show the color-changing temperature indicator comprises at least one liquid crystal that changes color when heated. Hilsum, however, teaches a temperature-indicating device that comprises at least one liquid crystal that changes color when heated (column 1, lines 6-8; column 2, lines 36-53). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use at least one liquid crystal in order properly indicate the temperature without having to rely on the reflection of a particular color as taught by Hilsum.

6. Claims 16-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke in view of Patel as applied to claim 1 above, and further in view of Jensen (US 5,785,527). Kipke and Patel disclose the dental treatment kit as

previously described, but fail to show the kit comprises at least one dental treatment composition preloaded within a syringe. Jensen, however, teaches a dental bleaching agent for use with a dental tray that is preloaded within a syringe (column 4, lines 29-46). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include a dental treatment composition preloaded within a syringe as part of the kit previously described in order to ensure that the desired quantity of dental bleaching agent is used during a procedure as taught by Jensen.

7. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke in view of Patel further in view of Jacobs (US 6,969,255). Kipke and Patel disclose the dental treatment kit as previously described, but fail to show the step of placing the dental tray over a person's teeth and forming an impression of said teeth. Jacobs, however, teaches placing the dental tray over the person's teeth when heated using either hot water (Figure 4A), a heat gun (Figure 4B), or a torch (Figure 4C) and forming an impression of the person's teeth within the dental tray (see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to place the dental tray over a person's teeth and form an impression of said teeth in order to ensure a proper fit as taught by Jacobs.

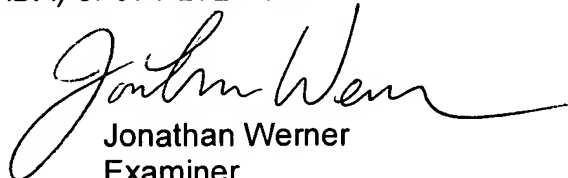
**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please refer to included form PTO-892 for all additional pertinent prior art related to dental trays and temperature indicators.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Jonathan Werner  
Examiner  
TC 3700

6/4/06

  
MELBA N. BUMGARNER  
PRIMARY EXAMINER